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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,326	07/20/1999	ROBERT E REITER	30435.54US14	2676

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EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,326

Applicant(s)

REITER ET AL

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7 and 18-86 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 18-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 69-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Claims 1-3, 7, 18-86 are pending.

Claims 1-3, 70-72, 77-81, 83-86 have been amended.

2. Claims 7, 18-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

3. Claims 1-3 and 69-86 are under examination.

4. The text of those sections of title 35, USC Code not included on the Office Action can be found in a prior Office Action.

Oath/Declaration

5. The Examiner acknowledges the filing of a new oath or declaration.

Rejections Withdrawn

6. The rejection of claims 1-3 and 69-86 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

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Response to Arguments

Priority

7. The examiner acknowledges the statements concerning priority on pages 5-8 of the response filed 12/26/01. Upon review of these statements the following priority dates are granted to the claims.

Claims 1, 3 3/98

Claim 2 3/98

Claim 69-70 3/98

Claims 71-72 2/99

Claim 73 2/99

Claim 74 3/98

Claims 75-80 3/98

Claims 81 and 86 7/99

Claim 82 and 83 3/98

Claim 84 7/99

Claim 85 3/98

Double Patenting

8. The rejection of claims 1-3 and newly submitted claim 74 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent 6,258,939 is maintained. It is noted that application 09/203939 is now patent 6,258,939.

The response filed 4/17/01 has been carefully considered but is deemed not to be persuasive. The response states "The rejection is presently untimely" (see page 8 of response). No terminal disclaimer has been filed and as such the rejection stands.

9. The rejection of newly added claims 71 and 72 under 35 U.S.C. 103(a) as being unpatentable over Au-Young (U.S. Patent 5,856,136, filed 7/3/96) and further in view of Green et al (Nature Genetics 7:13-21, 1994) is maintained.

The response filed 12/26/01 has been carefully considered but is deemed not to be persuasive. The response states that the examiner has not established a prima facie case of obviousness (see pages 10-11) and the response is summarized as to Au-Young did not disclose a function for PSCA and the response basically states that "with only a putative amino acid sequence of PSCA, and without knowing the function of the PSCA, there would be no suggestion, teaching or motivation to obtain any antibodies against PSCA" (see page 12 of response) and "even if Au-Young were to provide

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anything to one of ordinary skill more than an invitation to further research, which it does not, it is noted that Au-Young's hydrophobicity and hydrophilicity data of PSCA is not suggestive of the portions of the PSCA molecules which are recognized and bound by the antibodies of the invention." (see page 14 of response). In response to these arguments, the art of Au-Young does teach making antibodies to the protein which is SEQ ID NO:2 in the instant application. It was well known at the time of applicants invention to make antibodies to proteins. Au-Young does not need to teach the function of the protein of PSCA because it was well known to make antibodies to proteins for purification of the proteins and Au-Young teach the protein was a stem cell antigen and Au-Young does teach antibodies to the protein. A lack of statements in Au-Young of applicants function does not render the claims not obvious. It is also obvious that antibodies to the entire protein of Au-Young would bind to the recited regions because claims 1-3 encompass the entire protein sequence and one skill in the art could obtain monoclonal antibodies to regions of the protein. In addition, as stated in the Office Action mailed 6/12/01 on page 8 that Au-Young teach production of antibodies by determining regions of high immunogenicity and analysis to select epitopes such as those near the C-terminal or in hydrophilic regions as shown in Figure 5. Thus, one skill in the art would know that from the teaching of Au-Young of selecting immunogenic fragments such as those that are preferably 10 amino acids in length (see column 14) and from the analysis to select epitopes that are hydrophilic or near the C-terminal that peptides covering these regions (which encompasses the regions specified in the claims) could be used to elicit antibodies.

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The response further states that the claimed invention possesses unexpected advantages that the cited references does not teach (see pages 15-16 of response). In response to this argument, the response does not address whether the antibodies of Au-Young would not have the same properties. Absence evidence to the contrary the antibodies of Au-young would be expected to have the same properties.

The response further states that Green does not teach expression of function of PSCA and does not render the invention obvious. As discussed above Au-Young clearly teaches antibodies and in view of the claims, which have been amended to recite "humanized", (in which this term is broadly interpreted to be more humanlike) the teachings of Green et al read on the claims because human antibodies are humanized antibodies.

10. The rejection of claims 1-3, claims 77, 80-82, and 85-86 under 35 U.S.C. 103(a) as being unpatentable over Au-Young (U.S. Patent 5,856,136, filed 7/3/96) and further in view of Thorpe et al (Immunological Rev. 62:119-158, 1982) is maintained.

The response filed 12/26/01 has been carefully considered but is deemed not to be persuasive. The response argues the Au-Young reference as argued above and the same response would apply. Further the response states that Thorpe does not teach a function of expression of PSCA protein. In response to this argument, as discussed above Au-Young clearly teaches antibodies in view of Thorpe et al conjugates with the antibody of Au-Young would have been obvious for therapeutic purposes.

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11. The rejection of claims 1-3, 69-70, and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Au-Young (U.S. Patent 5,856,136, filed 7/3/96) is maintained.

The response filed 12/26/01 has been carefully considered but is deemed not to be persuasive. The response argues the Au-Young reference as argued above and the same response would apply.

12. The rejection of claims 76-79 and 82-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Au-Young (U.S. Patent 5,856,136, filed 7/3/96) and further in view of Helstrom et al (U.S. Patent 5,980,896, filed 6/14/96) is maintained.

The response filed 12/26/01 has been carefully considered but is deemed not to be persuasive. The response argues the Au-Young reference as argued above and the same response would apply. In addition the response states that Helstrom does not teach or suggest a PSCA protein of function. In response to this argument Au-Young teaches a function for the protein and in view of Hailstorm it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced an immunoconjugate of the antibody of Au-Young with 131I as taught by Helstrom et al because Au-Young teach an antibody directed to regions of SEQ ID NO:2 that one skill in the art would label the antibody with 131I as taught by Hailstorm to eradicate the tumor.

Conclusions

13. No Claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER